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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,319	08/08/2001	Gerard P. McNally	MCP-0289	5350

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
06/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/924,319	MCNALLY ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/3/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,14,15 and 18-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,14,15 and 18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Applicant refers to Example 1 as in support of the amendment "wherein the effective amount is sufficient to improve small bowel transit of digested matter" in claim 8. However, simply citing to said example is not sufficient to support the amendment to claim 8. The example used the transit distance of a charcoal marker to determine the effectiveness of the simethicone and bisacodyl, individually and alone. However, this method is not quantitative as it gives no information on the amount of marker at each point along the intestine and does not distinguish between an effect on stomach emptying and transit through the intestine. See Gaginella et al., page 1243. Notwithstanding the fact that a conclusion that small bowel transit of digested material may be obvious or expected from said data, the fact is that the Applicant has not set provided sufficient evidence which supports the conclusion that there is written description in the Specification of the amendment to claim 8. See In re Ruschig, 154 USPQ 118, 123 (CCPA 1967) (holding that while the claimed compound may have been easy enough to

imagine from the present Specification, the problem is that said compound was not described therein).

The Applicant refers to example 1 as support of the claim limitation where bisacodyl and simethicone are present in the ratio of 5 parts bisacodyl to from about 1 to about 3 parts of simethicone. The example sets forth specific amounts in mg/kg units with respect to the amounts used in testing the effect of simethicone and bisacodyl on small bowel transit rate not ranges in parts by weight. As such, it is not sufficient to merely state that Example 1 supports the amendment. The Applicant must show how the ranges were derived from said specific amounts in Example 1. In any case, the mere reference to Example 1, does not provide support for ranges in that Example 1 does not disclose ranges with respect to effect of simethicone and bisacodyl on small bowel transit rate. As such, the Applicant has not provided sufficient evidence to show that the ranges as set forth in the amendment were contemplated at the time the invention was filed. See In re Ruschig, 154 USPQ 118, 123 (CCPA 1967), cited above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8,14,15, 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 5,599,577) in view of Drug Launches (1993), Schmidt et al. (US 5,418,220), Holtmann et al., Gaginella et al. and Bortolotti et al. (translation provided).

Stevens et al. disclose the combination of simethicone, preferably in the range of 20 mg to about 125 mg per dosage unit, generally not to exceed 500 mg/day, to a patient suffering from gas and a pharmaceutical suitable for treatment of gastrointestinal disorders (Column 4, lines 38-54).

Drug Launches (1993) discloses the combination of simethicone and 10 mg of bisacodyl which is used to treat constipation, facilitate bowel motion and evacuation of intestines (Abstract).

Schmidt et al. (US 5,418,220) disclose that simethicone is effective in treating constipation (Column 2, lines 35-68, Column 3, lines 1-3, Claims 2,7,8).

Holtmann et al. teaches that simethicone is effective in treating dyspepsia associated with disturbance with GI motility in addition to its effects on gas-related symptoms and that simethicone may stimulate gastrointestinal motility (see entire reference, especially, Pg. 1464).

Gaginella et al.. discloses that bisacodyl significantly increased transit of marker through the small intestine (Pg. 1242).

Bortolotti et al. disclose an experiment in which simethicone is administered directed to the duodenum which resulted in inducing "phase 3" or "peristaltic activity front" intestinal motility (Pages 335-336). It is disclosed that that simethicone is capable of inducting at the intestinal level a motor activity similar to that of phase 3 of the propagated motor complex which is responsible for the clearing the intestinal lumen of undigested food residues, germs and gases produced by intestinal fermentation and the reaction of HCL in gastric juices with bicarbonate in the biliopancreatic juices (Pages 336-338). It is disclosed that simethicone acts through not only a humoral/hormonal mechanism but also through a local mechanism that stimulates motility. It

is disclosed that the excitatory-motor action explained by simethicone fits well with the known anti-foaming property of the same since both work together to effectively clear the intestinal lumen (Page 337).

The prior art discloses the combination of simethicone and a pharmaceutical suitable for treatment of gastrointestinal disorders. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of bisacodyl and simethicone for improving the small bowel motility or enhancing the small bowel motility increasing effect of bisacodyl. However, the prior art amply suggest the same as the prior art discloses the combination of simethicone in the claimed dose with pharmaceutical which is suitable for treatment of GI disorders, that bisacodyl and simethicone are suitable for treatment of constipation, that bisacodyl increases transit of a marker through the small intestine and that simethicone increases GI motility. As such, it would have been well within the skill of and one of ordinary skill in the art to modify the prior art as above with the expectation that the combination of simethicone and bisacodyl would be suitable for increasing small bowel motility and that simethicone, by increasing GI motility, would enhance the small bowel motility increasing effect of bisacodyl.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons of record set forth in the prior Office Action (1/3/2007) and the further reasons below.

Although the Applicant arguments in the prior Amendment (10/6/2006) were addressed in the prior Office Action (1/3/2007), it is noted that the Applicant had made various arguments concerning dosages used in the various references. One of ordinary skill in the art would have

knowledge of biology, including human and rat, pharmaceutics and chemistry. Since it is known from the combined teachings of the prior art that simethicone and bisacodyl, individually, induce small intestine motility, it is not outside the knowledge and skill of one of ordinary skill in the art to expect that the combination of the same would allow adjustment of dosages based on the desired effect of increasing small intestine motility and reduction of dosage due to the combined effect of simethicone and bisacodyl. Further, since simethicone and biscodyl are separately taught in the art to induce small intestine motility, there is ample reason to combine the same to increase small bowel motility and expect that the combination of simethicone with bisacodyl will enhance the small bowel enhancing effect of bisacodyl. See KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1397 (U.S. 2007) (the Supreme Court held that (1) any need or problem known in the field and addressed by the prior art can provide a reason for combining elements in the manner claimed; (2) it is error to assume that one of ordinary skill in the art in attempting to solve a problem would be led only to those elements designed to solve the same problem (common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple references together like pieces of a puzzle; a person of ordinary skill is not an automaton); (3) it is error to conclude that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try).

In the Interview (3/20/2007), the Applicant has indicated that there was a difference between gas motility and solid/liquid motility transit. Although the Examiner had indicated that this may be true and would consider a response directed to the same, the Examiner subsequently obtained a translation of a foreign reference by Bortolotti et al. As indicated above, Bortolotti et

al. discloses that simethicone has a direct effect on intestinal motility apart from its anti-foaming activity. As such, the Applicant's argument as to differences between gas motility and solid/liquid motility is without merit.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

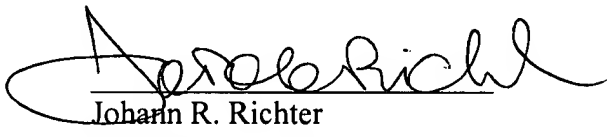
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
June 11, 2007



Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600